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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,131	11/22/2000	Ralph L. Bass	1136/8	2281

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N . 09/721,131	Applicant(s) BASS	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

~~A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE~~ 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

Examiner directs your attention to the following and reminds Applicant that both the description and summary of the invention should be commensurate with the claimed invention.

> Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
>
> Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

See also MPEP § 1302.01.

The title of the invention is not descriptive in that the claimed invention does not appear to be treatment of HIV but administration of sodium chloride to a patient with HIV. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of sodium chloride per se, i.e. as a nutritional supplement, does not reasonably provide enablement for treatment of HIV, i.e. reduction of viral titer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Despite the fact that more than a decade has past since the first cluster of cases of AIDS, neither a cure nor effective vaccine has been developed with treatment requiring compliance with multiple drug regimens (See Cecil Textbook of Medicine, Vol. 2 (21st Ed., 2000), pg. 1889). Further, it is generally accepted that the goal of anti-HIV therapy should ideally be to completely inhibit replication (Id. at 1934). It is not entirely clear whether the claims are intended to include within its scope the treatment of HIV, i.e. resulting in reduction of HIV titer. However, assuming that the same is within the scope of the claims, the Specification does not appear to show any working examples which show effective treatment of HIV in mammals much less humans. The examples which are provided appear to be hypothetical statements of what would occur as opposed examples of effective treatment in actual patients. Further, Applicant has not shown by what mechanism, theoretical or otherwise, how administration of sodium chloride results in reduction HIV nor has Applicant provided any data which shows that administration of NaCl caused the reduction of HIV as opposed to some other factor. Finally, Applicant indicates that the administration should result in circulating levels of NaCl within the range of about 0.05

uM to about 1.0uM, however, Examiner takes official notice that the normal serum concentration of sodium is 136-145 mEq/L and the normal serum concentration of chloride is 98-106 mEq/L and that less than 135 mEq/L of sodium can eventually lead to seizures and coma (See generally Drug Facts and Comparisons (54th Ed., 2000), pg. 116; Martindale (30th Ed., 1993), pg. 862). As such, if Applicant is correct then HIV infections and AIDS should have been nonexistent. Since this is not the case, a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the reasons above, given the current state of the art, the description does not appear sufficient, to the extent that the claims include within their scope the treatment of HIV per se, i.e. the reduction of HIV titer, to show that the administration of sodium chloride is effective in treating HIV per se in humans.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: "the dosage of NaCl must be less than the toxicity measured by a standard called LD50, namely the dosage that is lethal for 50% of the population . . . the dosage must also be less than the toxicity measured by a standard called TCLo, namely the dosage for oral consumption that is the lowest dosage that has produced toxic effects in humans .

. . 12357 mg of NaCl/kg of body weight/day for 23 days of continuous oral consumption" (See Specification, Pgs. 12, 13). Also, "the amount of S3 should be low enough so that the total daily dose of Se does not exceed 200 mcg" (See Specification, Pg. 10). The claims do not appear to contain a maximum dosage limitation of Sodium Chloride or Selenium which appears to be required by the Specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martindale (30th Ed., 1993) in view of Principles and Practice of Infectious Diseases (4th Ed., 1995), the acknowledged prior art, Morton Salt Product Data

Martindale (30th Ed., 1993) teaches that sodium chloride is used in the treatment of extracellular volume depletion, dehydration and sodium depletion which may occur during gastroenteritis (Pg. 862). It is taught that the suggested oral replacement dose of sodium chloride is about 1 to 2 g three times daily either with food or as solution with doses of up to 12 g daily in severe cases (Pg. 862). It is taught that glucose facilitates the absorption of sodium from the GI tract and solutions containing sodium chloride and glucose often with additional electrolytes are used for oral rehydration in acute diarrhea (Pg. 862). It is taught that other electrolytes and nutrients may be needed to replace those lost because of diarrhea or gastro-intestinal disorders,

including bicarbonates, calcium, magnesium, phosphate, potassium and proteins (Pgs. 851-861, 1033, 1034).

Principles and Practice of Infectious Diseases (4th Ed., 1995) teaches that the incidence gastroenteritis in patients with HIV infection is high and that HIV infection is associated with diarrhea and that diagnosis is performed using endoscopy or colonoscopy (Pgs. 1230, 1231).

Applicant acknowledges that it is well known that a person with HIV infection often will develop a Selenium deficiency which is associated with dialated cardiomyopathy (Pg. 10, lines 10-12).

Drug Facts and Comparisons (1998) teaches that tablet forms of sodium chloride are available, including a slow release form containing 410 mg sodium chloride and 150 mg potassium chloride (Pg. 54). It is taught that oral electrolyte mixtures are also available which contain sodium, potassium, chloride, citrate, sugars and flavorings (Pgs. 55, 56).

Morton Salt Product Data teaches that food grade salt contains sodium chloride and can contain trace amounts of calcium sulfate, calcium chloride, magnesium chloride, calcium, magnesium, copper and/or iron.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the periodic administration of sodium chloride so as to introduce the sodium chloride to the metabolism of persons having HIV infection. However, the prior art amply suggests the same as it is known that persons having HIV infection typically are electrolyte, including sodium chloride, depleted. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as

above depending on the nutritional needs of the patient, palatability, ability to swallow, severity of the condition and the use of different formulations also depending on the above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
December 12, 2001

JOHN PAK
PRIMARY EXAMINER
GROUP 1600